APPENDIX A

CHART SUMMARIZING DEFENDANTS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS AND PLAINTIFFS' RESPONSES

NO.	STATEMENT	PLAINTIFFS' RESPONSE	EVIDENCE CITED IN SUPPORT OF DENIAL?	CONCLUSION
1	In February 1969, the Department of Health, Education and Welfare ("HEW") issued a report observing: "[W]holesale prices are listed in company catalogs and price lists, but these generally represent maximum prices. They serve merely as an umbrella beneath which actual prices are set by quantity discounts, hospital discounts, government discounts, two-for-the-price-of-one deals, rebates, and other special arrangements." "Where acquisition cost was a factor in the reimbursing formula, this was generally presumed to be the listed wholesale price, although it is understood that this list price has little if any relationship to the actual acquisition cost." "Pharmacists usually apply. . . a percentage markup, or margin, system. The markup for most items stocked in pharmacies averages about 50 percent of cost; for prescription drugs, it ranges from 65 to 100 percent or more of acquisition cost." "[T]hese listed prices rarely have any realistic relationship with actual acquisition costs." "[M]any vendors have traditionally established their dispensing compensation as a percentage-usually 65 to 100 percent or more – of the acquisition cost of a prescription drug product. It is based on the philosophy that the marketing of prescription drugs is, in general, not significantly different from the marketing of any other commodity. Although it has certain disadvantages, application of the percentage markup approach has been found acceptable to many governmental and private drug programs."	Admitted.		**ADMITTED.**
2	On November 27, 1974, it was reported in the Federal Register that, among other things, average wholesale price ("AWP") was "in excess of actual acquisition cost to the retail pharmacist."	Admitted.[1]		**ADMITTED.**
3	On July 31, 1975, it was reported in the Federal Register that, among other things: "Average wholesale price is not currently determined by surveying drug marketing transactions	Admitted.[1,2]		**ADMITTED.**

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	(i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesale for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers."			
4	In December 1980, the Comptroller General of the United States reported, among other things, that AWPs were 15 to 18 percent higher than the prices at which pharmacists could obtain drugs.	Admitted.[2]		**ADMITTED.**
5	In 1984, the Office of Inspector General ("OIG"), Office of Audit, issued a report to alert United States Department of Health and Human Services ("HHS") management officials "to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of average wholesale prices (AWP) in determining program reimbursement for prescription drugs."	Admitted.[1,2]		**ADMITTED.**
6	In its 1984 Report, the OIG also states, among other things, that: "[W]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." 99.6 percent of the purchases that it had studied "were made at prices about 16 percent below AWP" and that these "drug purchases ranged from as little as 0.23 percent below AWP to as much as 41.78 percent below AWP." "[P]harmacies do not purchase drugs at the AWP published in the 'Bluebook,' 'Redbook,' or similar publications. Thus, AWP cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices." It "recommended that the regulations be revised to include language that will preclude the general use of AWP."	Admitted.[1,2]		**ADMITTED.**
7	On July 31, 1987, it was reported in the Federal Register that state agencies had questioned the use of the *Red Book* and *Blue Book* because they believed that the average wholesale prices listed in these publications had been often overstated.	Admitted.[2]		**ADMITTED.**
8	In a November 13, 1987 letter, Don M. Newman, then-Under Secretary of HHS, states that "AWP seldom represents true costs."	Admitted.[2]		**ADMITTED.**
9	In a March 10, 1988 memorandum, HCFA, Region VI, reports, among other things, that:	Admitted.		**ADMITTED.**

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	"The DHHS Office of Inspector General ("HHS-OIG") Audit in 6 states . . . shows that 99.6 percent of the pharmacy purchases were made at prices averaging 16 percent below the AWP." A "1985 Dallas Regional Office study of drug purchases in [two states] shows that, of 1,323 drug purchases, the average difference between AWP and what pharmacists generally paid was 12.53 percent." A "1985 Dallas Regional Office review of drug purchases in Louisiana revealed that (i) one chain pharmacy paid 20 percent below the AWP; (ii) one independent pharmacy received an average discount of 10 percent off AWP; and (iii) one discount pharmacy received an average discount of 15 percent off AWP." "In November 1982, 46 of the 49 states with a vendor drug program reimbursed drugs at the published AWP. Twenty-five (51 percent) of these states have now recognized that AWP is inflated and have established rates at a level below the published AWP." A "review of Texas pharmacies . . . found that the average pharmacy receives a discount of about 13 percent off AWP."			
10	During a September 21, 1988 reconsideration hearing on a Louisiana state plan amendment, an attorney for HCFA stated, among other things, that: "Since 1977 the Secretary of HHS has put everybody including the states on notice about Federal Register publications, that in the Secretary's opinion based on evidence available to him or her that the average AWP, average wholesale price, as published in the national drug compendia do not equate to the price currently being paid by providers."	Neither admitted nor denied.[2,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
11	During a September 21, 1988 reconsideration hearing on a Louisiana state plan amendment, Peter Rodler of HCFA stated, among other things, that "AWP is like the sticker price on an automobile."	Neither admitted nor denied.[2,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
12	During a September 22, 1988 reconsideration hearing on a Louisiana state plan amendment, Nancy Saltzman of HCFA stated, among other things, that "probably ninety to ninety-five percent of the purchases are made at prices below AWP, and that's confirmed by what wholesalers tell us."	Neither admitted nor denied.[1,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
13	In a May 16, 1989 letter, Louis W. Sullivan, then-Secretary of HHS, writes that "the published AWP is not an acceptable measure because it is frequently inflated and does not reflect the various incentives, sales promotions, discounts and allowances (other	Admitted.[2]		**ADMITTED.**

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	than discounts for cash or prompt payment) that are routine terms of purchasing in the drug marketplace."			
14	In a 1989 report, the Majority Staff of the Special Committee of Aging for the United States Senate reports that "the [Veteran's Administration] achieves an average discount of 41% off [AWP] for single source drugs and 67% off the published AWP for multiple source drugs . . . [and] hospitals, HMOs and nursing homes that contract with wholesalers achieve discounts up to 99% of AWP."	Admitted.[2]		**ADMITTED.**
15	In an October 1989 OIG report, Richard P. Kusserow, Inspector General, states, among other things, that: "[The] preponderance of the evidence demonstrat[es] that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent." "We continue to believe that AWP is not a meaningful payment level and that it should not be used for making reimbursements in either the Medicaid or the new Medicare drug program." An unidentified wholesaler was quoted as saying, "'AWP is a meaningless figure.'" An unidentified wholesaler was quoted as saying, "'[I]t is recognized in the industry that there are discounts off AWP . . . selling price is based on AWP less a discount or . . . cost plus a markup.'" A "top Pennsylvania Medicaid official was quoted . . . as saying the average wholesale price '. . . just doesn't mean anything. It has no connection to what pharmacies really purchase the drug for.'" "[W]e recommend that alternate reimbursement methods be studied and that consideration be given to using a reimbursement method other that AWP or permits AWP to be appropriately discounted for reimbursement purposes" and states that, "[o]ur ongoing work is exploring methods of reimbursement other than AWP."	Admitted.[2]		**ADMITTED.**
16	In the January 16, 1990 brief filed by the United States Department of Health and Human Services in *Louisiana v. Department of Health & Human Servs.*, No. 89-4566, the Government states: "The evidence in the record shows that published AWP significantly overstates the prices generally paid by providers and that alternative drug pricing methods will result in far more	Neither admitted nor denied.[1,2,3]		**ADMITTED.** *See* Local Civ. R. 56.1.

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	accurate estimates of pharmacy purchase prices." "The great weight of evidence in the record supports the Secretary's position that AWP significantly overstates the prices that pharmacists are generally paying for prescription drugs." "As a HCFA official stated at the administrative hearing, AWP has become like the 'sticker price on an automobile. It is the very highest price that anyone would be expected to pay for a drug product.'" "As the disapproval letter indicates, what changed over time was not the Secretary's interpretation of the EAC requirement, but rather the weight of the evidence that AWP overstates drug prices and thus is not a reasonable "best estimate" of acquisition cost."			
17	In *Louisiana v. Department of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990), the Fifth Circuit observes, among other things, that: "[There has been considerable doubt for a number of years whether AWP provides the closest estimate of the price generally and currently paid by pharmacists for drugs." "[W]e need only determine whether the Administrator's finding that Louisiana's AWP was not the closest estimate withstands our limited appellate scrutiny. We think it does. The 1984 report of the Office of Inspector General offered statistical evidence that AWP was an inaccurate measure. The Social and Rehabilitative Service had reached the same conclusion a decade earlier, when it proposed the 1975 regulations."	Admitted.[2]		**ADMITTED.**
18	In an October 1, 1990 letter to Senator Lloyd Bentsen, then-Chairman of the U.S. Senate Committee on Finance, Gail R. Wilensky, then-HCFA Administrator, writes: "AWP is not an acceptable measure because it is frequently inflated and does not reflect the various incentives, sales promotions, discounts, and allowances (other than discounts for cash or prompt payment) that are routine terms of purchasing in the drug marketplace."	Admitted.		**ADMITTED.**
19	In 1990, Congress passed the Omnibus Budget Reconciliation Act of 1990 which established a Medicaid rebate program and required participating manufacturers to report their "best prices" taking into account discounts, free goods, and rebates.	Admitted.[2]		**ADMITTED.**
20	On June 5, 1991, HHS reports in the Federal Register that: It had "considered [several] options for drugs under the fee schedule," but had "decided that it is not practical for us to consider establishing a national drug fee schedule at this time."	Admitted.		**ADMITTED.**

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	It would "instruct all carriers to base payment for drugs on 85 percent of the national average wholesale price . . .." It "welcome[d] comments regarding the appropriate discount."			
21	In *In re Oklahoma Department of Human Servs.*, 1991 WL 634860 (HHS Dep't App. Bd. Aug. 13, 1991), the Departmental Appeals Board of HHS, among other things, states: "One problem was states' use of the 'average wholesale price' (AWP) of drugs as a measure of acquisition cost." "A federal audit conducted in 1983 in six states (not including Oklahoma) showed that pharmacists' drug costs averaged about 16 percent below the AWP."	Admitted.[1,2,3]		**ADMITTED.**
22	In *In re Arkansas Department of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991), the Departmental Appeals Board of HHS concluded that "the State could not reasonably consider the AWP to be its 'best estimate' since the State was aware that pharmacists generally paid less than that amount and since the State had no pertinent records to support a determination that the AWP represented the price generally and currently paid."	Admitted.[1,2,3]		**ADMITTED.**
23	On November 25, 1991, it was reported in the Federal Register, that HCFA had "received a great many comments on [the drug reimbursement] issue, primarily from oncologists indicating that our 85 percent standard was inappropriate." "The thrust of most of the comments was that many drugs could be purchased for considerably less than 85% of AWP—particularly multi-source drugs—while others were not discounted." Commenters had "suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not." "Some commenters also suggested that [an] add-on payment was needed to account for shortfalls in chemotherapy administration payments." "Without adequate compensation, commenters suggested many physicians would perform the service in hospital outpatient departments at substantially higher costs."	Admitted.[2,4]		**ADMITTED.**

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24	On November 25, 1991, as reported in the Federal Register, HCFA set reimbursement for drugs at the "estimated acquisition cost or the national average wholesale price."	Admitted.		**ADMITTED.**
25	In a July 1992 report to the Chairman of the Senate Committee on Finance, the General Accounting Office ("GAO") states, among other things, that: "Our review showed (1) some oncologists have treated cancer patients in hospital inpatient and outpatient settings when, by clinical standards, they could have received treatment in the office; (2) financial factors influence the oncologist's choice of treatment setting; and (3) treatment in the hospital inpatient setting was most expensive to Medicare in three case studies." "What is clear from our results, however, is that HCFA's reimbursement policies for chemotherapy have unintended consequences that extend beyond whether and how much oncologists are reimbursed by Medicare. Specifically, the policies may affect where a cancer patient gets treated and, as a result, Medicare costs for that patient's care."	Admitted.		**ADMITTED.**
26	In an August 1992 report, the GAO states that "discounts for the drugs in our study ranged from 2 percent to 99 percent off the AWP."	Denied.	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
27	In an October 1992 report, OIG states, among other things, that: "Our review of 30 randomly selected dialysis facilities disclosed that most of the separately billed drugs administered during May 1991 were purchased at prices below AWP. The median cost for two of the more frequently administered brand name drugs ranged from 15 percent to 20 percent less than AWP. Instructing the fiscal intermediaries (FI) to set the reimbursement limit at the EAC rather than the AWP for selected drugs appears to be a reasonable approach to controlling Medicare program expenditures."	Admitted.[2]		**ADMITTED.**
28	In a November 6, 1992 report, OIG states: "AWP is not a reliable indicator of the cost of a drug to physicians."	Admitted.[2]		**ADMITTED.**
29	Appendix III to HHS-OIG Report, *Physicians' Costs for Chemotherapy Drugs* A-02-91-01049 (Nov. 6, 1992) reflects discounts off of AWP ranging from 9 to 83 percent.	Admitted.[2]		**ADMITTED.**
30	In a March 1993 report for Congressional Committees, the GAO states: "For the Illinois pharmacies, the amount by which reimbursement exceeded purchase costs ranged from 10 to 23 percent. For the Maryland pharmacies, the range was from 11 to 34 percent."	Neither admitted nor denied.[2]		**ADMITTED.** *See* Local Civ. R. 56.1.

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	"[R]epresentatives of all nine pharmacies contended that because of insufficient dispensing fees they used the excess reimbursements to cover the drugs' dispensing costs."			
31	In a February 22, 1994 letter, HCFA informs a doctor that it "has not yet implemented the estimated acquisition cost portion of [42 CFR § 405.517] or provided carriers with specific instructions on how to execute this segment of the drug payment policy."	Admitted.		**ADMITTED.**
32	On March 15, 1994, HCFA instructs all Regional Administrators for Medicare how to determine "acquisition cost of drugs" so that they can base payment on the lower of the estimated acquisition cost or the AWP as required by 42 CFR § 405.517.	Admitted.		**ADMITTED.**
33	On August 8, 1994, HCFA instructs all Regional Administrators for Medicare to immediately "suspend data collection efforts requested in the March 15, 1994 memorandum" because it needs approval from the Executive Office of Management and Budget to conduct the survey.	Admitted.		**ADMITTED.**
34	On August 12, 1994, HCFA instructs all Part B carriers to immediately "suspend data collection efforts requested in the March 15, 1994 memorandum" because it needs approval from the Executive Office of Management and Budget to conduct the survey.	Admitted.		**ADMITTED.**
35	A February 26, 1996 article in Barron's states that "without the large drug markups, [oncology] practices would have been in the red."	Neither admitted nor denied.[1,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
36	In a May 1996 report, OIG finds, among other things, that "Medicare allowances for prescription drugs may not be appropriate."	Admitted.[2]		**ADMITTED.**
37	In another May 1996 report, OIG finds that "AWP exceeded invoice prices for brand name drugs by 17.5 percent" and "generic drugs by 41.4 percent."	Admitted.		**ADMITTED.**
38	In a June 1996 report, OIG finds that "the generic drug prices that five buying groups negotiated ranged from 56 to 70 percent less than the $0.43 Medicare allowed per milliliter of albuterol sulfate."	Admitted.[2]		**ADMITTED.**
39	In a July 1996 letter to a doctor, HCFA responds that "at this time, there should be no drugs paid based on EAC."	Admitted.[2]		**ADMITTED.**
40	A June 10, 1996 article of Barrons states that, "[f]or many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices [to manufacturers] that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims."	Admitted.[2,3]		**ADMITTED.**
41	In an August 12, 1996 letter, Dr. Grant Steffen writes to Jill Merrill of HCFA that "[t]wo years have passed and there has been no visible attempt at collaborating" on a survey to determine physicians' acquisition costs.	Neither admitted nor denied.[1,3]		**ADMITTED.** *See* Local Civ. R. 56.1.

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42	In an October 2, 1996 letter, Ven-A-Care of the Florida Keys, Inc. writes then-HCFA Administrator Bruce Vladeck that, among other things, "Medicare and Medicaid programs are continuing to make excessive reimbursements to providers for infusion and inhalation pharmaceuticals." "[W]e found that Medicare's reimbursement was excessive and in many cases provided profit margins of more than 500% and, in some instances, more than 1000%."	Denied.[1,3]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
43	During hearings before the Committee on Finance for the U.S. Senate regarding the President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare, the following testimony was given: "[T]he AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a "sticker" price set by drug manufacturers and published in several commercial catalogs. . . . We believe that physicians should be paid for their professional services and not derive a profit from drugs furnished incident to their professional services. Also, the current payment rules allow an increase in the AWP even if the cost to the physician remains constant. This creates an incentive for physicians to furnish the most profitable drugs. Our proposal would remove this incentive so that the decision to furnish a particular drug is more directly based on medical considerations."	Admitted.[2]		**ADMITTED.**
44	In an April 1997 report, OIG estimates that the invoice price for brand name drugs was a "national average of 18.3 percent below AWP."	Admitted.[2]		**ADMITTED.**
45	In a June 1997 Report, relating to the Balanced Budget Act of 1997, the Committee on the Budget of the House of Representatives reports that: "Medicare reimbursement for the top 10 oncology drugs ranges from 20% to nearly 1000% per dosage more than acquisition costs." The Congressional Budget Office assumed that drug manufacturers would "raise AWP for their products to compensate for the payment cuts."	Denied.[4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
46	In a June 11, 1997 letter to Bart McCann of HCFA, Phyllis S. Tyzenhouse states: "[P]hysicians and health care providers, can negotiate with the pharmaceutical companies for a much lower price than lower-volume purchasers. Instead of being reimbursed by Medicare for the actual cost, the acquisition price, they receive a far larger sum based on the average wholesale price."	Denied.[2,3]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.

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	"One large facility purchases a medication, Lupron, for the treatment of prostate cancer, at the discounted price of $400 for three-months of injections to an individual patient, and is reimbursed by Medicare for $1,200."			
47	Public Law No. 105-33 § 4566(a) (codified as 42 U.S.C. § 1395u(o)(1)), sets reimbursement for certain drugs or biologicals at "95 percent of the average wholesale price."	Admitted.[2]		**ADMITTED.**
48	If enacted, the Medicare and Medicaid Beneficiary Protection Act of 1997, H.R. 2632, 105th Cong. § 206 (1997) would have limited payment to the lower of the "actual acquisition cost" or "average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1,2]		**ADMITTED.** *See* Local Civ. R. 56.1.
49	In a December 1997 report, OIG states, among other things, that: "The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." "[W]e've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities." "Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed."	Admitted.[2,4]		**ADMITTED.**
50	In a December 1997 radio address, President Clinton states: "Sometimes the waste and abuse aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs – overpayments that cost taxpayers hundreds of millions of dollars . . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for the drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price."	Admitted.[2]		**ADMITTED.**
51	In the same radio address referenced in paragraph 50 above, the President said he intends to send Congress "the same legislation I sent last year – legislation that will ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
52	In a January 1998 transmittal, HCFA states that the change from 100% of AWP to	Admitted.[2]		**ADMITTED.**

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	95% of AWP "recognizes the fact that the AWP is not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary."			
53	If enacted, the Stop Medicare Overpayment Act of 1998, H.R. 3139, 105th Cong. § 2 (1998), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
54	If enacted, the Medicare Fraud and Overpayment Act of 1998, H.R. 3471, 105th Cong. § 2 (1998), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
55	If enacted, the Medicare Prescription Drug Coverage Act of 1998, H.R. 4753, 105th Cong. § 7 (1998), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
56	If enacted, the Medicare Fraud and Overpayment Act of 1998, S. 1788, 105th Cong. § 2 (1998), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
57	If enacted, the Medicare Waste Tax Reduction Act of 1998, S. 2335, 105th Cong. § 6 (1998), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
58	If enacted, the Medicare Fraud and Reimbursement Reform Act of 1999, H.R. 2229, 106th Cong. § 2 (1999), among other things, would have limited payment to the lowest of "the actual acquisition cost . . . to the person submitting the claim for payment for the drug or biological" or "95 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.

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59	In an August 1998 report, OIG finds: "Medicare will allow between 56 to 550 percent more than the Department of Veterans Affairs will pay for generic versions of albuterol sulfate in 1998." ___ Decl. ¶ 51 (quoting HHS-OIG Report, *Are Medicare Allowances for Albuterol Sulfate Reasonable?*,OEI-03-97-00292, at 7 (Aug. 1998) (Ex. 55). "Medicare allowed up to 333 percent more than acquisition costs available for albuterol sulfate in 1998."	Admitted.[2]		**ADMITTED.**
60	On November 2, 1998, HHS reports in the Federal Registrar that based on "a series of OIG reports spanning the past 10 years, it is clear that the AWP is higher than the amount typically paid for drugs by physicians who bill the program."	Admitted.[2]		**ADMITTED.**
61	On December 1998, HCFA instructs Carriers to start reimbursing drugs and biologicals on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as required by 42 CFR 405.517.	Admitted.		**ADMITTED.**
62	In a 1999 report to Congress, Donna Shalala, then-Secretary of HHS, states: There is "no consistent or predictable relationship" between provider acquisition costs and AWPs. "[T]he AWP is not a well-defined concept nor is it regulated in any way. OIG reports that the AWP is set by the manufacturer as a suggested price and published in various commercial sources. However, it is not truly an average of wholesale prices because very few purchasers actually pay this amount." "AWP is used as a benchmark, with negotiated prices often expressed in terms of AWP minus a certain percentage. OIG found that the AWP published in the commercial sources for 22 of the top drugs paid by Medicare is not representative of any price that is actually charged by wholesalers to their customers. . . . On average, for the 22 drugs in the OIG study, Medicare payment at the AWP allowed a markup of 41 percent above the drugs' wholesale catalog price advertised to the physicians and suppliers who bill Medicare."	Admitted.		**ADMITTED.**
63	If enacted, the Medicare Waste Tax Reduction Act of 1999, S. 1451, 106th Cong. § 4 (1999), among other things, would have limited payment to the lowest of "the actual acquisition cost" or "83 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
64	If enacted, the Fiscal Responsibility Act of 1999, S. 1959, 106th Cong. § 124 (1999),	Neither admitted		**ADMITTED.**

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	among other things, would have limited payment to the lowest of "the actual acquisition cost" or "83 percent of the average wholesale price of such drug or biological, as determined by the Secretary."	nor denied.[1]		*See* Local Civ. R. 56.1.
65	If enacted, the Discretionary Spending Offsets Act for Fiscal Year 2000, H.R. 3085, 106th Cong. § 716 (1999), among other things, would have stricken the phrase "is equal to 95 percent of the average wholesale price" from 42 U.S.C. § 1395u(o)(1) and inserted the phrase "is equal to . . . for 1998 and 1999, 95 percent of the average wholesale price" and "for 2000 and each subsequent year, 83 percent of the average wholesale price."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
66	In a May 31, 2000 letter to Representative Thomas Bliley, Chairman of the Commerce Committee for the U.S. House of Representatives, Donna Shalala, then-Secretary of HHS, informs Congress the actions HHS will take in response to the Department of Justice and State Medicaid Fraud Control Units' investigations into drug pricing: HHS will send "this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances." HHS is also "consulting with the Department of Justice and HHS Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare rates."	Neither admitted nor denied.[1]		**ADMITTED.** *See* Local Civ. R. 56.1.
67	In a June 2000 report, OIG states that "the Medicare reimbursement for albuterol is almost seven times greater than the VA price." Medicare could "save between $47 million and $209 million by lowering its reimbursement amount for albuterol to prices available through other sources." And, "20 percent of these savings would directly benefit Medicare beneficiaries through reduced copayments."	Neither admitted nor denied.[1,2]		**ADMITTED.** *See* Local Civ. R. 56.1.
68	In a July 28, 2000 letter to then-Secretary Shalala, Senator Saxby Chambliss and various other members of Congress writes: ". . . [O]ncologists are chronically underpaid for their drug administration services in treating cancer patients — a fact that is widely recognized, including in your letter announcing the plan to reduce reimbursement. If reimbursement for drugs is drastically reduced, many physicians will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient and cost-effective treatment option."	Neither admitted nor denied.[3]		**ADMITTED.** *See* Local Civ. R. 56.1.
69	In a August 3, 2000 letter to then-Secretary Shalala, Senators Christopher Bond and John Ashcroft write:	Neither admitted nor denied.[2,3]		**ADMITTED.** *See* Local Civ.

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	"As you know, in the Balanced Budget Act of 1997 (BBA), Congress instructed HHS to base Medicare reimbursement for cancer drugs on 95% of the "average wholesale price," or AWP, a term widely understood and indeed defined by HHS manuals to reference amounts reflected in specified publications." "It is disturbing that HHS would now seek to circumvent Congressional actions by redefining AWP. We see no basis for such action in any of our previous legislation, and certainly HHS' unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate."			R. 56.1.
70	On September 5, 2000, in a statement before Congress, Senator John Ashcroft states: HCFA proposed to "reduce drastically Medicare reimbursement rates for cancer drugs by unilaterally changing the definition of 'average wholesale price,' which is at the heart of the current reimbursement formula." "[T]hese margins have been used to help cover costs for professional services, which are inadequately reimbursed according to the cancer community and eliminating them would "force doctors to send seniors with cancer out of the community centers where they now receive care and into more expensive in-patient settings." The proposed Cancer Care Preservation Act "will guarantee that HCFA cannot implement any reductions to Medicare reimbursement for outpatient cancer treatment unless those changes are developed in concert with the General Accounting Office, the Medicare Payment Advisory Commission, and representatives of the cancer care community . . ."	Admitted.[2]		**ADMITTED.**
71	In a September 8, 2000 transmittal, HCFA instructs carriers "to consider" the pricing data derived by the Department of Justice and the National Association of Medicaid Fraud Control Units relating to 32 drugs referenced in an attached pricing list, as "another source in determining your January, 2001 quarterly update for the 32 drugs." HCFA, however, expresses "concern about access to care related to the DOJ's wholesale prices for 14 chemotherapy drugs and 3 clotting factors (Attachment 2), due to other Medicare payment policies associated with the provision of these drugs for the treatment of cancer and hemophilia." Thus, it instructs carriers "not to consider at this time using the DOJ data for these drugs (Attachment 2) to establish your Medicare allowances while we further review these concerns and develop alternative policies."	Admitted.[2]		**ADMITTED.**
72	In a September 8, 2000 letter to Congress, Nancy-Ann Min DeParle, then-Administrator of HCFA, states that CMS has "gathered information on many of the	Admitted.[2]		**ADMITTED.**

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	drugs reviewed by DOJ" and has "concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate."			
73	In a November 17, 2000 transmittal, HCFA instructs the Carriers "NOT [to] use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data your usual source." It further states that "[w]hile we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source."	Admitted.[2]		**ADMITTED.**
74	The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, § 429(c) (2000), among other things, barred HHS from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Part B until the issue of Medicare drug reimbursement could be further studied.	Admitted.[2]		**ADMITTED.**
75	As set forth by 42 C.F.R. § 405.517 (2001), "[p]ayment for a drug or biological that is not paid on a cost or prospective payment basis" was "based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological."	Admitted.[2]		**ADMITTED.**
76	In a September 2001 report, the GAO observes, among other things, that: "While physicians—particularly oncologists—and other health care providers such as pharmacy suppliers acknowledge that they can purchase drugs for prices lower than Medicare payments, they contend that they need drug payments in excess of their actual costs to compensate for inadequate or nonexistent Medicare payments for administering the drugs. Further, they suggest that some providers, particularly those who purchase drugs in low volume, may not have access to low drug prices, because the lowest prices reflect volume discounts and other factors. They assert that beneficiary access could be impaired if Medicare payments are reduced."	Admitted.[2]		**ADMITTED.**
77	After studying the 20 highest dollar volume Medicare Part B drugs, the GAO states, in the same report referenced in paragraph 76 above that, "[f]or most physician-administered drugs, the average discount from AWP ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 percent and 86 percent."	Admitted.[2]		**ADMITTED.**
78	In a 2001 statement to Congress, Thomas Scully, then-Administrator of CMS, states:	Admitted.[2]		**ADMITTED.**

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	"Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare payments are based, are vastly higher than the amounts that drug manufacturers and wholesalers actually charge providers."			
79	In the same statement referenced in paragraph 78 above, Administrator Scully states that: "Some affected physicians and providers have suggested that they need these Medicare 'drug profits' to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. I believe we need to pay appropriately for both the drugs and the services related to furnishing the drugs."	Admitted.[2]		**ADMITTED.**
80	In an October 2001 report, the GAO notes, among other things, that Congress directed that three studies (including the study that resulted in the October 2001 report) be conducted in response to the HCFA's steps to lower Medicare drug payments as a result of "investigations that revealed that Medicare's payments were much higher than the actual acquisition costs for" Medicare-covered drugs and which "would have substantially reduced revenues to oncologists."	Admitted.[2]		**ADMITTED.**
81	In March 14, 2002 testimony before the Finance Committee of the U.S. Senate, then-HCFA Administrator, Thomas Scully testifies that: "Many of these providers rely on cross subsidies to survive basically in the Medicare business." "[T]he acknowledged transfer and cross subsidy from AWP for oncologists has resulted in our [payments for services] being somewhat artificially low for practice expenses."	Denied.[3]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
82	Appearing before the Senate Finance Committee Subcommittee on Health on March 14, 2002, Administrator Scully states that: "[T]he current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries."	Denied.[3,4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
83	Appearing before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate, Leslie G. Aronovitz, Director, Health Care—Program Administration and Integrity Issues for GAO, testified: "In concept, such a payment method has the potential to be market-based and self-adjusting. The reality is, however, that AWP is neither an average nor a price that wholesalers charge. Because the term AWP is not defined in law or regulation, there is no requirements or	Admitted.[2]		**ADMITTED.**

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	conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Given the latitude manufacturers have in setting AWPs, Medicare's payments are often not related to market prices that physicians and suppliers actually pay for the products."			
84	In an October 4, 2002 letter to then-HCFA Administrator Scully, Glenn M. Hackbarth, Chairman of Medicare Payment Advisory Commission ("MedPAC"), writes: "A series of studies by the GAO [and OIG] have provided ample evidence that Medicare pays far more than market price for the outpatient prescription drugs that it covers under Part B." "The Commission recognizes that changes in the drug payment method may have implications for other parts of the payment system, for example, if inadequate payments for some services are cross-subsidized by overpayments for drugs."	Admitted.[2]		**ADMITTED.**
85	A January 2, 2003 House Report summarizing the hearings on the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") states: "The Balanced Budget Act of 1997 (P.L. 105-33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of the average wholesale price (AWP) for the drug. The AWPs, however, are not defined by law or regulation. The AWPs are reported by drug manufacturers to organizations that publish the data in compendia. Medicare carriers use the published data in calculating payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. … In addition, AWPs do not reflect the discounts, rebates, or "charge backs" that manufacturers and wholesalers customarily offer to providers. Therefore, AWPs represent neither average prices nor prices charged by wholesalers."	Admitted.[2]		**ADMITTED.**
86	On page 2 of its February 28, 2003 report to Senate Committee on Finance Staff, MedPac states, among other things, that the "current system leads to payments that overstate provider acquisition costs" but that "payments for drug administration may be too low."	Admitted.[2]		**ADMITTED.**
87	In a June 2003 report to the Congress, MedPac states: AWP "does not have to correspond to any transaction price or average transaction price." "AWP has never been defined in statute or regulation." "Because there is no official calculation method, CMS potentially can use alternate sources of	Admitted.[2]		**ADMITTED.**

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	information like market surveys to establish new AWPs for setting Medicare payment rates." "[P]ayments [for drug administration] may be too low, particularly for administration of chemotherapy. Physicians have argued that they need the high payments for drugs to offset inadequate payments for provision of these services."			
88	A July 15, 2003 report of the House Committee on Ways and Means states: "The Balanced Budget Act of 1997 (BBA 97, P.L. 105-33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Law or regulation does not define AWP. Publishing organizations report AWPs provided by drug manufacturers. Medicare carriers use the published data to payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices."	Admitted.[2]		**ADMITTED.**
89	The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. § 1395 (2006) ("MMA"), sets drug reimbursement at "106 percent" of the lesser of "average sales price" or "wholesale acquisition price" for single source drugs or biologicals.	Admitted.[2]		**ADMITTED.**
90	The MMA, among other things, provides payment for physician services, including "drug administration services."	Admitted.[2]		**ADMITTED.**
91	In a May 19, 2005 letter to President George W. Bush, Congress states, among other things, that CMS "increased payments for chemotherapy administration services" and "launched a $300 million demonstration project for 2005 that pays community cancer clinics for assessing important cancer-related systems."	Neither admitted nor denied.[1,2,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
92	In a January 2006 report to Congress, MedPac summarizes how Medicare payment changes have affected oncology services.	Denied.[1,2,3]		**ADMITTED.** *See* Local Civ. R. 56.1.
93	Plaintiffs' expert, Raymond S. Hartman ("Hartman"), opined that market participants – including Medicare – "expected" that AWP would not exceed ASP by more than 30 percent.	Denied.[2]	"Ex. 86 at the cited paragraphs does not so state."	
94	Plaintiffs' expert Hartman opined that, for purposes of the Medicare classes, there is no legally permissible "spread" between AWP and ASP "by statute."	Denied.[2,4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
95	Plaintiffs' expert Hartman opined that ASP is the functional equivalent of EAC.	Denied.[2,4]	No evidence cited.	**ADMITTED.** *See* Local Civ.

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				R. 56.1.
96	Plaintiffs' expert Hartman opined in his December 15, 2005 liability report that drugs with spreads between ASP and AWP of up to 30% are "untainted by the AWP scheme" – even in the Medicare Part B context.	Denied.[2,4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
97	Plaintiffs' expert Hartman, in his supplemental expert report, substituted in a 0% yardstick for the 30% liability "yardstick" in the Medicare context and altered the way he calculated ASPs.	Denied.	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
98	Plaintiffs' expert Harman testified that he "was asked by counsel to do that supplemental," report and that it did not represent his opinion about the proper measure of liability. Hartman also admitted that the "alternative" 0% yardstick scenario resulted in assigning liability even when AWPs were well within market expectations.	Denied.[4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.
99	A corporate representative for Blue Cross/Blue Shield of Massachusetts testified that he understood, as early as 1995, that AWP was an "artificial price" commonly referred as "ain't what's paid." He testified further that he knew AWP was a reimbursement benchmark, that it was not an average of the prices charged by wholesalers, and that it did not bear any predictable relationship to acquisition cost.	Denied.[2,4]	No evidence cited.	**ADMITTED.** *See* Local Civ. R. 56.1.

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